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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/779,581

Applicant(s)

SHANNON, J. GROVER

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. See page 18, paragraph #0091; pages 19-20, paragraph #0099; page 27, paragraph #00123. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). If the material is not considered by Applicant to be essential material, a statement on the record would obviate this objection (See MPEP 608.01(p)(I)).

2. The disclosure is objected to because of the following informalities:

At page 12, ¶ 0067, line 5, "1990<" appears to be a typographical error.

At page 22, ¶ 00111, line 2, "stearoyl" appears to be misspelled because it is spelled differently than in the claims (i.e. claim 20).

At page 24, ¶ 00120, the section title "Tissue Culture of Soybeans" does not appear to describe the subsequent information and appears to be a typographical error.

Appropriate correction is required.

Claim Objections

3. Claim 5 is objected to because of the following informalities: The limitation "wherein cells of the tissue culture are from" appears to unduly limit Applicant's invention because said limitation appears to not encompass subsequent cell generations in culture. Amending this limitation to recite -- are produced from -- is suggested to more clearly state the invention. Appropriate correction is suggested.
4. At claims 14 and 25, line 2, "of:" should be -- of -- as a matter of form.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 20, 21, 28 and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 20, line 4, the limitation "stearyl-ACP desaturase" renders the claim indefinite because the specification teaches that the transgene must be an antisense gene of "stearoyl-ACP desaturase" to modify fatty acid metabolism, hence the metes and bounds of the claim are unclear (page 22, ¶ 00111 of the specification).

Claim 21 is indefinite because said claim does not state that the produced soybean plant has modified fatty acid metabolism or modified carbohydrate metabolism, hence the metes and bounds of the claim are unclear.

At claim 28, line 7, the limitation "stearyl-ACP desaturase" renders the claim indefinite because the specification teaches that the nucleic acid molecule must be an

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antisense gene of "stearoyl-ACP desaturase" to modify fatty acid metabolism, hence the metes and bounds of the claim are unclear.

Claims 28 and 29 are indefinite because it is unclear of the soybean line that comprises a nucleic acid molecule is transgenic for said nucleic acid molecule, or if such molecule is an inherent property of the other soybean plant, hence the metes and bounds of the claims are unclear.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 8 and 9 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a hybrid soybean seed and plant grown from said seed, said seed produced by crossing the exemplified soybean line designated 4283008 with a different soybean plant.

Applicant describes soybean line designated 4283008, and methods of crossing said soybean line designated 4283008 with other soybean plants (page 3, 2nd paragraph of the specification).

Applicant does not describe the genus of hybrid soybean seed and plants grown therefrom as broadly claimed.

The claims are drawn to hybrid soybean seeds and plants produced from said seeds wherein one of the parents is 42830086 and the other parent plant is not specified. The hybrid plants are not defined by genomic structure or by phenotypic characteristics, and it is unclear what characteristics of 4283008 would be present in the claimed hybrid seeds and plants. Due to the segregation and recombination of the parent genomes during meiosis, one cannot predict what traits or combinations of traits will be passed on to any given hybrid seed and plant. In fact, each hybrid seed derived from a cross between two genetically distinct parent plants will have unique combinations of characteristics. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). Hence, it is unclear how Applicant can describe the genus of claimed progeny plants by only describing one parental soybean plant.

See *University of California v. Eli Lilly*, 119 F.3d 1567, 43 USPQ 2d 1405 (Fed. Cir. 1997), where it states: "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed

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compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

9. Claims 8, 9, 20, 21 and 23-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a hybrid soybean seed and plant grown from said seed, said seed produced by crossing the exemplified soybean line designated 4283008 with a different soybean plant. Applicant claims a method of modifying fatty acid metabolism in the exemplified soybean plant comprising transforming said soybean plant with a transgene encoding stearyl-ACP desaturase. Applicant claims methods of introducing a desired trait into soybean line 4283008 comprising crossing said soybean line 4283008 with another soybean line comprising a desired trait/nucleic acid molecule and backcrossing to said soybean line 4283008, and a soybean plant produced therefrom.

Applicant teaches soybean line designated 4283008, and methods of crossing said soybean line designated 4283008 with other soybean plants (page 3, 2nd paragraph of the specification). Applicant teaches a method of modifying fatty acid metabolism by transforming a plant with an antisense gene of "stearoyl-ACP desaturase" (page 22, paragraph 00111 of the specification). Applicant teaches physiological and morphological characteristics of soybean line 4283008 in the Variety Description Information on page 10 of the specification.

Applicant does not teach the genus of hybrid soybean seed and plants grown therefrom as broadly claimed. Applicant does not teach how to make and use a soybean plant transformed with a transgene encoding stearyl-ACP desaturase, or produced by ingressing such a transgene into soybean line 4283008 in a backcrossing method. Applicant does not teach enough physiological and morphological characteristics of soybean line 4283008 to enable one of skill in the art at the time of Applicant's invention to use the methods of claims 23 and 28, and make the soybean plants of claims 24 and 29 as broadly claimed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

At claims 8 and 9, Applicant provides no examples of progeny of the exemplified soybean cultivar 4283008 in the specification. The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The nature of the art at the time of Applicant's

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invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few if any individuals having the desired genotype may be found in a large F_2 or S_0 population and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebart, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3). Segebart (U.S. Patent 5,367,109, column 2, lines 60-64) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary qualities (column 4, 1st and 2nd paragraphs). Applicant admits that the processes which lead to the final step of marketing and distribution usually take from eight to 12 years from the time the first cross is made (page 2, ¶ 0006 of the specification). Applicant admits that the breeder can theoretically generate billions of different genetic combinations via crossing, selfing and mutations and that the breeder has no direct control at the cellular level (page 2, ¶ 0008 of the specification). Finally, Applicant admits that a breeder of ordinary skill in the art cannot predict the final resulting lines he develops, except possibly in a very gross and general fashion (page 2, ¶ 0009 of the specification). Hence, given Applicant limited guidance, the nature of the

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invention, the relative skill of one of skill in the art, the unpredictability of the art, the lack of working examples for the claimed invention and the breadth of the claims, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants invention to make and use the myriad of progeny of soybean cultivar 4283008 as broadly claimed.

At claims 20, 21, 28 and 29, Applicant only teaches how to make and use a soybean plant with modified fatty acid metabolism by transforming a soybean plant with an antisense gene of "stearoyl-ACP desaturase", and provides no guidance on how to make and use such a soybean plant by expressing a sense nucleic acid molecule in a soybean plant.

At claims 23-29, Applicant provides no working examples of introducing a desired trait into soybean line 4283008 by crossing soybean line 4283008 with another soybean line to produce a progeny soybean having the desired trait and backcrossing said progeny soybean with soybean line 4283008 repeatedly to produce a backcross progeny plant that comprises the desired trait and all of the physiological and morphological characteristics of soybean line 4283008 listed in the Variety Description Information as determined at the 5% significance level when grown in the same environmental conditions. The Variety Description Information on page 10 of the specification teaches only a few quantitative traits of soybean line 4283008 by which one of skill in the art can determine at the 5% significance level, the majority of the traits are controlled by single loci and are shared by many other soybean lines and thus do not adequately distinguish soybean line 4283008 from others. Hence, given the lack of

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working examples, the nature of the invention, the limited teachings of Applicant about physiological and morphological characteristics of soybean line 4283008, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to identify enough physiological and morphological traits of soybean line 4283008 that distinguish it from other soybean lines in order to practice the claimed methods and make and use the claimed soybean plants having the desired trait as claimed.

See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

10. Claims 1-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that Applicant intends to deposit the plant but there is no indication in the specification as to the conditions under which such a deposit is to be made by which a determination of enablement of such a deposit can be assessed (page 30 of the specification).

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a

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statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

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Conclusion


11. The claims are free of the prior art, which neither teaches nor fairly suggest soybean line 4283008, or methods of use.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.


DAVID H. KRUSE, PH.D.
PATENT EXAMINER
AU 1638

David H. Kruse, Ph.D.
23 July 2004

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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